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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/722,045

10/04/1996

VIRGINIA FREEMAN

P26,487-A USA

3646

7590

03/01/2006

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EXAMINER

EBRAHIM, NABILA G

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/722,045	Applicant(s) FREEMAN ET AL.	
	Examiner Nabila G. Ebrahim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,13,23 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,13,23 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments of the claims received on 11/21/05 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 6, 23, 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks et al. US 5354556.

Sparks teaches a controlled release formulation comprising microparticles wherein the particle size average diameter is 0.1 microns or greater (100 nanometer), (see abstract). The controlled release powder includes the same drugs nifedipine (col. 4, line 60), morphine (col. 5, line 3), and biodegradable polylactides (col. 4, line 4). The composition is provided as effervescent tablets (col. 7, line 52). Sparks comprised various drug groups in his invention. For example, he included diltiazem, nifedipine (claim 3), verapamil (col. 4, line 59), morphine, codeine sulfate, dihydrocodeine tartrate, oxycodone, buprenorphine (col. 5, lines 1-5), and captopril (col. 4, line 64).

Though Sparks discloses the microparticles, he did not disclose a microcapsule, however, the specification of the current application defines the term microcapsule as being used to include the terms "microsphere", "microparticles", "nanosphere" and "nanoparticle", and adds that these terms do not necessarily refer to any structural

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relationship between the drug and the encapsulating polymer in a matrix (structure).

Rather, these terms simply refer to a particle (micron sized or less) in which the drug is entrapped in a polymer (Specification, page 3, lines 3-9).

In addition, the reference does not disclose the D50 percentage of the 100 and 900 nanometers or the adjusted pH. Using microparticles within the range of D 50 recited by the claims of the instant application with a reasonable expectation of success would have been obvious to one of ordinary skill in the art to advance the uniformity in dissolution and absorption rates since particles of the same or similar size and configuration are known to provide the best release and absorption profiles. In addition, Sparks stated that the particle size might be controlled in a number of ways. For example, the particles size may be controlled by the rate of mixing, the viscosity during manufacturing, the active ingredient particle size or volatility of the solvent (col. 7, lines 20-25). Since the composition is a controlled-release, it is expected that a skilled artisan would be able to adjust the pH of the formulation.

✓ because sparks' teachings included particles in the same size (100 nanometer), the same drugs (diltiazem, nefidipine, verapamil, morphine, codeine sulphate, dihydrocodeine tritarate, oxycodone, buprenorphine, and captopril) and the same polymer (the pylactide), it would have been obvious to a skilled artisan to expand these teaching of Sparks and use a D50% in the recited range to advance the homogeneity of the composition, its dissolution and absorption rates since particles of the same or similar size and configuration are known to provide the best dissolution and release-profile. In addition the artisan will be motivated by the disclosure of Sparks that particles

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size might be controlled in a number of ways like controlling the rate of mixing, the viscosity during manufacturing, the active ingredient particle size or volatility of the solvent (col. 7, lines 20-25).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

2/21/06


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER